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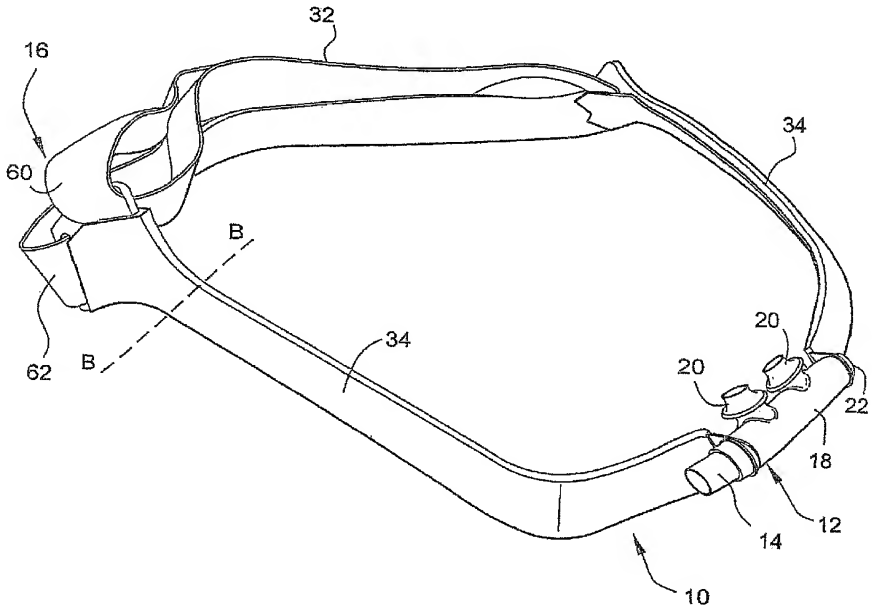
[Continued on next page]

(54) Title: NASAL ASSEMBLY



(57) Abstract: A nasal assembly (10) includes a patient interface (12) including a hollow body (18) that defines an air chamber and a pair of nozzles (20) supported by the hollow body (18). Each nozzle (20) includes a conical tip (28) structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Headgear (16) is provided to the patient interface (12) so as to maintain the patient interface (12) in a desired position on the patient's face in use. The hollow body (18) is bendable to adjust a position of the nozzles (20) in use.

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NASAL ASSEMBLY

CROSS REFERENCE TO APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/726,182, filed October 14, 2005, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a nasal assembly used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NPPV).

BACKGROUND OF THE INVENTION

[0003] Some nasal assemblies used in the treatment of SDB are designed for insertion into the nasal passages of the patient. Air or other breathable gas is supplied by a blower and passed along a flexible conduit to the nasal assembly.

[0004] The nasal assembly generally includes a relatively rigid shell, e.g., a frame, and a pair of nozzles (which may be in the form of nasal pillows, nasal prongs, cannula, or nasal puffs) that are mounted on the rigid shell and structured to be inserted into the nasal passages of the patient. The nozzles are usually held in place using a headgear assembly, the relatively rigid shell and headgear assembly being joined using some form of connector.

[0005] A key factor in the efficacy of therapy and compliance of patients with therapy is the comfort and fit of the nasal assembly. While there are a large number of nasal assemblies designed for adults, there are relatively few designed to suit children.

SUMMARY OF THE INVENTION

[0006] One aspect of the present invention relates to a nasal assembly suitable for children or pre-adults.

[0007] Another aspect of the present invention relates to a nasal assembly that provides comfort and softness, stability, and/or unobtrusiveness.

[0008] Another aspect of the present invention relates to a nasal assembly including a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body. Each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Headgear is provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use. The hollow body is bendable to adjust a position of the nozzles in use.

[0009] Yet another aspect of the present invention relates to a nasal assembly including a tubular air chamber that provides at least one lateral inlet and a pair of nozzles supported by the tubular air chamber. Each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. The conical tip includes an outlet opening. The outlet opening has a circular shape.

[0010] Still another aspect of the present invention relates to a nasal assembly including a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body. Each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Headgear is provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use. The patient interface contacts the patient's face only at the nose and below the nose in use.

[0011] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0013] Fig. 1 is a perspective view of a nasal assembly according to an embodiment of the present invention;

[0014] Fig. 2 is a front perspective view of the patient interface of the nasal assembly shown in Fig. 1;

[0015] Fig. 3 is a cross-sectional view of the patient interface shown in Fig. 2;

[0016] Fig. 4 is a rear perspective view of the nasal assembly shown in Fig. 1 and showing exemplary dimensions of an embodiment;

[0017] Fig. 5 is an enlarged top view of the patient interface of the nasal assembly shown in Fig. 1;

[0018] Fig. 6 is a front perspective view of the nasal assembly shown in Fig. 1 mounted to a patient's face;

[0019] Fig. 7 is a side view of the nasal assembly shown in Fig. 1 mounted to a patient's face;

[0020] Fig. 8 is a plan view of a yoke of the headgear of the nasal assembly shown in Fig. 1 and showing exemplary dimensions of an embodiment;

[0021] Fig. 9 is a plan view of a yoke ring of the yoke shown in Fig. 8; and

[0022] Fig. 10 is a schematic view of a breathing system including the nasal assembly shown in Fig. 1

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0023] Fig. 1 illustrates a nasal assembly 10 according to an embodiment of the present invention. As illustrated, the nasal assembly 10 includes a patient interface 12 that provides an effective seal with the patient's nasal passages, an air delivery connecting member 14, e.g., elbow, provided to one end of the patient interface 12 to deliver breathable gas into the patient interface 12 for breathing by the patient, and headgear 16 provided to the patient interface 12 so as to maintain the patient interface 12 in a desired position on the patient's face.

[0024] The overall architecture of the nasal assembly 10 is similar to the nasal assembly disclosed in U.S. Patent Application Nos. 10/781,929, filed February 20, 2004, and 11/101,657, filed April 8, 2005, the entireties of both being incorporated herein by reference. In contrast, the nasal assembly 10 is modified in size and shape for children or pre-adults in the range of 2-3 years old. However, the nasal assembly 10 may be designed for children or pre-adults in the range of 2-12 years old. Also, aspects of the present invention may be applicable to other breathing arrangements and other age groups.

1. Patient Interface

[0025] As best shown in Figs. 2 and 3, the patient interface 12 includes a hollow body or barrel 18 that defines an air chamber and a pair of nozzles 20 supported by the hollow body 18. In an embodiment, the hollow body 18 and nozzles 20 may be formed separately from one another, e.g., by silicone in an injection molding process, and then attached to one another. However, the hollow body 18 and nozzles 20 may formed as a one-piece structure such that the hollow body 18 is integrally formed in one-piece along with the nozzles 20, e.g., by silicone in an injection molding process.

1.1 Hollow Body

[0026] The hollow body or barrel 18 is in the form of a silicone cylindrical tube. In the illustrated embodiment, one end of the hollow body 18 is provided with a plug 22 and the other end is provided with a connector or retainer 24 that supports the air delivery connecting member 14. The positions of the plug 22 and connector 24 may be interchanged, according to preference, e.g., the typical sleeping position of the patient. One or more vents 90, e.g., four vent openings with 2 mm diameters, may be provided in the hollow body 18 for CO_2 washout (see Fig. 3). In the illustrated embodiment, the vents 90 are provided on a side of the hollow body 18 opposite the nozzles 20. However, other vent arrangements are possible.

1.2 Nozzles

[0027] Each nozzle 20 is in the form of a nasal prong and includes a cylindrical tube portion 26 provided to the hollow body 18 and a conical tip 28 structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Each conical tip 28 has a generally cone-like shape with a flange or widened portion 30. However, the nozzles 20 may have other suitable forms to sealingly communicate with the patient's nasal passages, e.g., nasal pillows, cannula, nasal puffs.

[0028] As best shown in Figs. 4 and 5, each conical tip 28 is substantially circular in plan view to conform to a child's nasal passages and ensure substantially even loading into a child's nose. This arrangement dictates that the tube portion 26 is also circular in shape so that the load is transferred evenly to the conical tip 28.

[0029] In the illustrated embodiment, the nozzles 20 extend out from the hollow body 18 in parallel relation (see Figs. 2 and 3). However, the nozzles 20 may be angled with respect to the hollow body 18 to properly position the nozzles with respect to the nasal passages of the patient. Also, a space G is provided between the nozzles 20 to accommodate the patient's septum. As shown in Fig. 3, the spacing G may be in the range of 1-6 mm, e.g, 5.3 mm.

1.3 Hollow Body and Nozzle Flexibility

[0030] The hollow body 18, e.g., formed of silicone, is relatively flexible. This flexibility allows the hollow body 18 to bend or flex which allows adjustment of the nozzles 20 attached thereto, e.g., angle nozzles 20 with respect the patient's nose in use. The nozzles 20, e.g., formed of silicone, are also relatively flexible to properly position the nozzles 20 with the nasal passages of the patient.

[0031] The hollow body 18 may also be rotatable relative to the headgear to adjust a position of the nozzles in use. Rotation of the hollow body 18 may improve seal and comfort of the nozzles in the patient's nose in use.

1.4 Child or Pre-Adult Sizing

[0032] The hollow body 18 and nozzles 20 are suitably shaped and sized to accommodate features of a child or pre-adult, e.g., 2-12 years old, preferably 2-3 years old. For example, Fig. 3 illustrates parameters of an embodiment of the hollow body 18 and nozzles 20. In an embodiment the hollow body 18 has a wall thickness of about 1 mm, a length F of about 35-40 mm, e.g., 38 mm, an inside diameter E of about 6 mm, and an outside diameter D of about 8 mm. Each nozzle 20 has a wall thickness of about 0.5 mm, an inside diameter B at the conical tip outlet opening of about 4 mm, an inside diameter C at the tube portion of about 5 mm, and an outside diameter A at the widened portion of about 10 mm. Although specific dimensions and ranges are provided for an embodiment of the hollow body 18 and nozzles 20, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application.

2. Headgear

[0033] As best shown in Figs. 1, 6, and 7, the headgear 16 includes headgear straps 32 and headgear yokes 34 provided between the headgear straps 32 and the patient interface 12.

2.1 Headgear Yokes

[0034] As shown in Figs. 6 and 7, the yokes 34 extend from respective ends of the hollow body 18 to above the patient's ears where they engage the headgear straps 32. The yokes 34 provide a stable connection between the headgear straps 32 and the hollow body 18 in order to secure the patient interface 12 at the correct orientation on the patient's face.

[0035] The yokes 34 are relatively rigid elements that are each constructed from a rigid or semi-rigid material. In the illustrated embodiment, the yokes 34 are manufactured of a relatively rigid or stiff plastic or metal material, e.g., polycarbonate or nylon, having a thickness of 0.8 mm. However, other materials of greater or less rigidity are also possible. Also, the yokes 34 may be constructed from multiple layers, e.g., two or more layers (one of which may be silicone based, for comfort), or may be constructed from a single layer of substantially rigid material. In general, the yokes 34 are constructed of a material that will retain its shape in use.

[0036] The inside surface of each yoke 34, i.e., the surface facing the patient's face in use, may be lined with foam. In an embodiment, the entire yoke 34 may be wrapped in foam. The foam provides a soft contact surface for contacting the patient's face. In an embodiment, the foam may be a nitrogen blow medical grade open celled foam, e.g., PEBA Foam 0.8 mm manufactured by ALVEO.

[0037] In an alternative embodiment, the yokes may be provided by a bendable wire covered with cloth, foam, leather, etc. The bendable wire may be bent or adjusted to correspond with the facial contour of the patient.

2.1.1 Yoke Shape and Sizing

[0038] Each yoke 34 includes upper and lower ladder locks 36, 38 at one end for attachment to the headgear straps 32 (e.g., see Fig. 7), and a yoke ring 40 at the opposite end for attachment to the hollow body 18 (e.g., see Figs. 2-6 and 9).

[0039] As illustrated, each yoke 34 has a bent or curved configuration along its length. Specifically, each yoke 34 has an approximate right angle bend (as indicated by arrow A) from the yoke ring 40 so that a portion 42 of each yoke 34 extends generally parallel with a longitudinal axis of the hollow body 18, as best shown in Fig. 4. Then, each yoke 34 is curved from the bent portion 42 so that it will curve around the patient's cheeks in use. As shown in Fig. 4, each of the yokes 34 makes an angle of about 120° with respect to the longitudinal axis of the hollow body 18. Preferably, the yokes 34 are spaced from the patient's cheeks in use, and only the conical tips 28 and a central portion of the hollow body 18 contact the patient's face in use. That is, the yokes 34 are contoured such that the yokes 34 do not contact the patient's face from the yoke ring 40 to the line B-B adjacent the patient's ears in use (see Fig. 1). However, one or more portions of the yokes 34 could potentially contact the patient's face if extra support were needed.

[0040] The yokes 34 are suitably shaped and sized to accommodate features of a child or pre-adult, e.g., 2-12 years old, preferably 2-3 years old. For example, Fig. 8 illustrates exemplary dimensions of an embodiment of a yoke 34. Although specific dimensions of the yoke 34 are shown in Fig. 8, it is to be understood that these dimensions are merely exemplary and other dimensions are possible depending on application.

2.1.2 Yoke Connection to Patient Interface

[0041] The plug 22 and connector 24 are adapted to connect the yokes 34 to the hollow body 18. As best shown in Fig. 3, the plug 22 includes a tube portion 44 and a head portion 46. The plug 22 is engaged with one yoke 34 by inserting the tube portion 44 through the opening 48 (e.g., see Fig. 9) in the yoke ring 40. The plug 22 is then engaged with an end of the hollow body 18 by inserting the tube portion 44 into an end of the hollow body 18 such that the protrusion 50 provided on the tube portion 44 interacts with a groove 52 provided in the hollow body 18 for sealing and/or locking purposes. Moreover, the head portion 46 of the plug 22 and the end of the hollow body 18 sandwich the yoke ring 40 therebetween to secure the yoke ring 40 to the hollow body 18.

[0042] Similarly, the connector 24 includes a first tube portion 54, a flange 56, and a second tube portion 58. The connector 24 is engaged with the other yoke 34 by inserting the first tube portion 54 through the opening 48 in the yoke ring 40. The connector 24 is then

engaged with the other end of the hollow body 18 by inserting the first tube portion 54 into the other end of the hollow body 18. The first tube portion 54 may be retained to the other end of the hollow body 18, e.g., by friction fit, adhesive, mechanical interlock, etc. Moreover, the flange 56 of the connector 24 and the other end of the hollow body 18 sandwich the yoke ring 40 therebetween to secure the yoke ring 40 to the hollow body 18. The second tube portion 58 is adapted to connect to the air delivery connecting member 14, e.g., by friction fit, adhesive, mechanical interlock, etc.

[0043] In use, the yoke rings 40 may rotate on the respective plug 22/connector 24 to adjust the position of the yokes 34 with respect to the hollow body 18. Also, as noted above, the positions of the plug 22 and connector 24 may be interchanged according to preference.

2.2 Headgear Straps

[0044] As best shown in Figs. 1 and 7, the straps 32 include an upper strap portion 60 provided between the upper ladder locks 36 of the yokes 34, and a lower strap portion 62 provided between the lower ladder locks 38 of the yokes 34. In use, the upper strap portion 60 extends over the top of the patient's head and the lower strap portion 62 extends around the back of the patient's head.

[0045] The strap portions 60, 62 may be connected to respective ladder locks 36, 38 in any suitable manner, e.g., wrapped around respective ladder locks 36, 38 in a known manner. Fastening of the strap portions 60, 62 may be provided by a hook and loop material, e.g., Velcro®. However, other adjustment arrangements are possible.

3.0 Connecting Member and Air Delivery Tubing

[0046] As schematically shown in Fig. 10, a small bore tube 70 is connected to the patient interface 12 via the air delivery connecting member 14. The air delivery connecting member 14 may be an elbow that provides an angle, e.g., in the range of 5-90°. However, the air delivery connecting member 14 may be a straight connecting tube. The small bore tube 70 is communicated, e.g., via a connector 72, with a larger bore tube 74 associated with the flow generator 76. In use, the flow generator 76 provides pressurized air, e.g., in the range of 4-10 cmH_2O, to the patient interface via the tubes 70, 74.

[0047] In the illustrated embodiment, the small bore tube 70 has substantially the same diameter as the hollow body 18 of the patient interface 12, e.g., 6 mm inside diameter. The small bore tube 70 may have a length of 15-25 mm, e.g., 24 mm. The larger bore tube 74, e.g., 22 mm inside diameter, may have a length of 20-30 mm, e.g., 20 mm.

4.0 Children or Pre-Adult Use of Nasal Assembly

[0048] The nasal assembly 10 includes several features that facilitate use for children or pre-adults. For example, the nasal assembly 10 is structured such that only the conical tips 28 and a central portion of the hollow body 18 may contact the patient's face in use. That is, the patient interface 12 contacts the patient's face at the nose and below the nose only. This arrangement makes the nasal assembly 10 non-obtrusive so it doesn't apply pressure to regions of the patient's face that may lead to discomfort.

[0049] Another feature is the circular configuration of the nozzles 20. This arrangement more closely follows the shape of children's nasal passages which are more circular than elliptical for example.

[0050] Yet another feature is the flexibility of the hollow body 18 which facilitates adjustment of the nozzles 20.

[0051] Still another feature is that the parameters of the patient interface 12 and headgear 16 are sized and/or shaped to accommodate features of a child or pre-adult. In addition, the smaller bore air delivery tube 70, e.g., 6 mm vs. larger 15 mm provided in known nasal assemblies, provides air pressure at a level suitable for children or pre-adults, e.g., 4-10 cmH_2O.

[0052] The nasal assembly provides an interface having comfort and softness, stability, and unobtrusiveness. In an embodiment, comfort and softness may be enhanced by including a textile sock or covering around at least a portion of the assembly and/or a yoke constructed of or covered with a silicone material. In an embodiment, stability may be enhanced by including headgear having a bonnet design, e.g., headgear formed with a cupping portion at the back to better grip the occipital region of the child's head. In the illustrated embodiment, the nasal assembly is unobtrusive because it does not cover the eyes of a child or pre-adult. In an embodiment, unobtrusiveness may be enhanced by providing an air delivery connecting member or inlet tube that is integral with the above-noted silicone yoke,

that extends up to a manifold provided at the top/back of a patient's head, that is collapsible (such as collapsible conduit headgear described in PCT Publication No. WO 2005/099801, published October 27, 2005, the entirety of which is incorporated herein by reference), that is not collapsible, that is unattached to the headgear except where it meets the patient interface, and/or that is attached to the headgear at any point along the headgear.

[0053] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A nasal assembly, comprising:

a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body, each nozzle including a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use; and

headgear provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use,

wherein the hollow body is bendable to adjust a position of the nozzles in use.

2. The nasal assembly according to claim 1, wherein the patient interface and headgear are sized and shaped for children or pre-adults in the range of 2-12 years old.

3. The nasal assembly according to any one of claims 1-2, wherein the patient interface and headgear are sized and shaped for children or pre-adults in the range of 2-3 years old.

4. The nasal assembly according to any one of claims 1-3, wherein the hollow body and nozzles are formed of silicone.

5. The nasal assembly according to any one of claims 1-4, wherein the hollow body and nozzles are formed separately from one another and then attached to one another.

6. The nasal assembly according to any one of claims 1-5, wherein each nozzle includes a cylindrical tube provided to the hollow body that supports the conical tip.

7. The nasal assembly according to any one of claims 1-6, wherein the conical tip includes an outlet opening, the outlet opening having a circular shape.

8. The nasal assembly according to claim 7, wherein the outlet opening has an inside diameter of about 4 mm.

9. The nasal assembly according to any one of claims 1-8, wherein the conical tip includes a widened portion having an outside diameter of about 10 mm.

10. The nasal assembly according to any one of claims 1-9, wherein the hollow body has an inside diameter of about 6 mm.

11. The nasal assembly according to any one of claims 1-10, wherein one end of the hollow body is provided with a plug and the other end is provided with a connector that supports an air delivery connecting member.

12. The nasal assembly according to claim 11, wherein positions of the plug and connector may be interchanged.

13. The nasal assembly according to any one of claims 1-12, wherein the headgear includes headgear straps and relatively rigid headgear yokes provided between the headgear straps and the patient interface.

14. The nasal assembly according to claim 13, wherein the yokes are constructed from rigid or semi-rigid material.

15. The nasal assembly according to any one of claims 13-14, wherein the yokes are constructed from polycarbonate.

16. The nasal assembly according to any one of claims 13-15, wherein the yokes are at least partially covered with foam.

17. The nasal assembly according to any one of claims 13-16, wherein each of the yokes makes an angle of about 120° with respect to a longitudinal axis of the hollow body.

18. The nasal assembly according to any one of claims 12-17, wherein each of the yokes includes a yoke ring for attachment to the hollow body.

19. The nasal assembly according to claim 18, wherein the yoke ring of one yoke is sandwiched between a plug and an end of the hollow body.

20. The nasal assembly according to claim 19, wherein the yoke ring of the other yoke is sandwiched between a connector and the other end of the hollow body, and wherein the connector is adapted to support an air delivery connecting member.

21. The nasal assembly according to claim 20, wherein positions of the plug and connector may be interchanged.

22. The nasal assembly according to any one of claims 13-21, wherein the headgear straps include an upper strap portion that extends over the top of the patient's head in use and a lower strap portion that extends around the back of the patient's head in use.

23. The nasal assembly according to claim 22, wherein the upper and lower strap portions are connected to the yokes via a ladder lock arrangement.

24. The nasal assembly according to any one of claims 1-23, wherein the patient interface contacts the patient's face only at the nose and below the nose in use.

25. The nasal assembly according to any one of claims 1-24, wherein the hollow body is rotatable relative to the headgear to adjust a position of the nozzles in use.

26. A nasal assembly, comprising:

a tubular air chamber that provides at least one lateral inlet; and

a pair of nozzles supported by the tubular air chamber, each nozzle including a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use,

wherein the conical tip includes an outlet opening, the outlet opening having a circular shape.

27. A nasal assembly, comprising:

a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body, each nozzle including a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use; and

headgear provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use,

wherein the patient interface contacts the patient's face only at the nose and below the nose in use.

28. A breathing system, comprising:

a flow generator;

air delivery tubing; and

a nasal assembly according to any one of claims 1-27.

29. The breathing system according to claim 28, wherein the air delivery tubing includes a first delivery tube coupled to the hollow body or tubular air chamber, the first delivery tube having an inside diameter that is substantially the same as an inside diameter of the hollow body or tubular air chamber.

30. The breathing system according to claim 29, wherein the hollow body or tubular air chamber have an inside diameter of about 6 mm.

31. The breathing system according to any one of claims 28-30, wherein the air delivery tubing includes a second delivery tube coupled between the first delivery tube and the flow generator, the second delivery tube having an inside diameter that is larger than the inside diameter of the first delivery tube.

32. The breathing system according to claim 31, wherein the second delivery tube has an inside diameter of about 22 mm.

33. The breathing system according to any one of claims 28-32, wherein in use the flow generator provides pressurized air in the range of 4-10 cmH_2O to the patient.

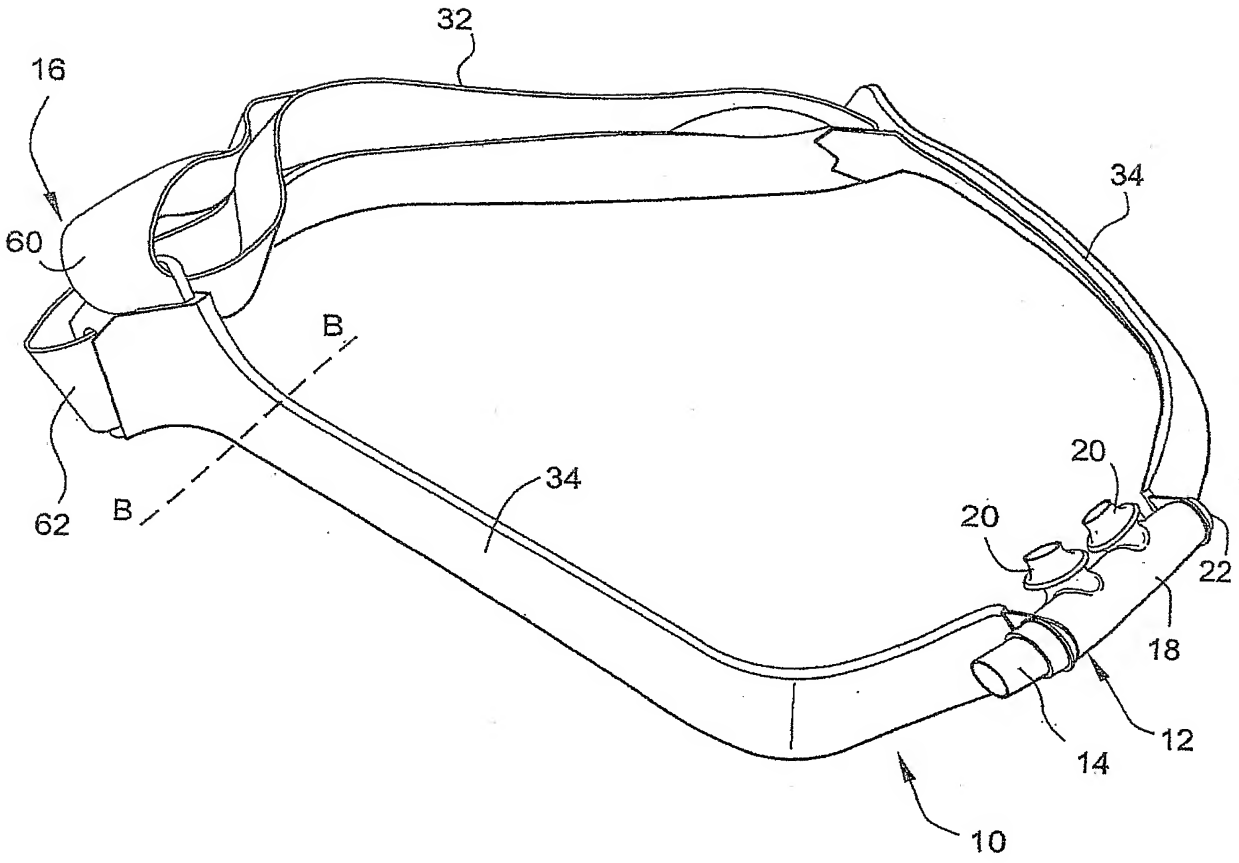

Fig.1

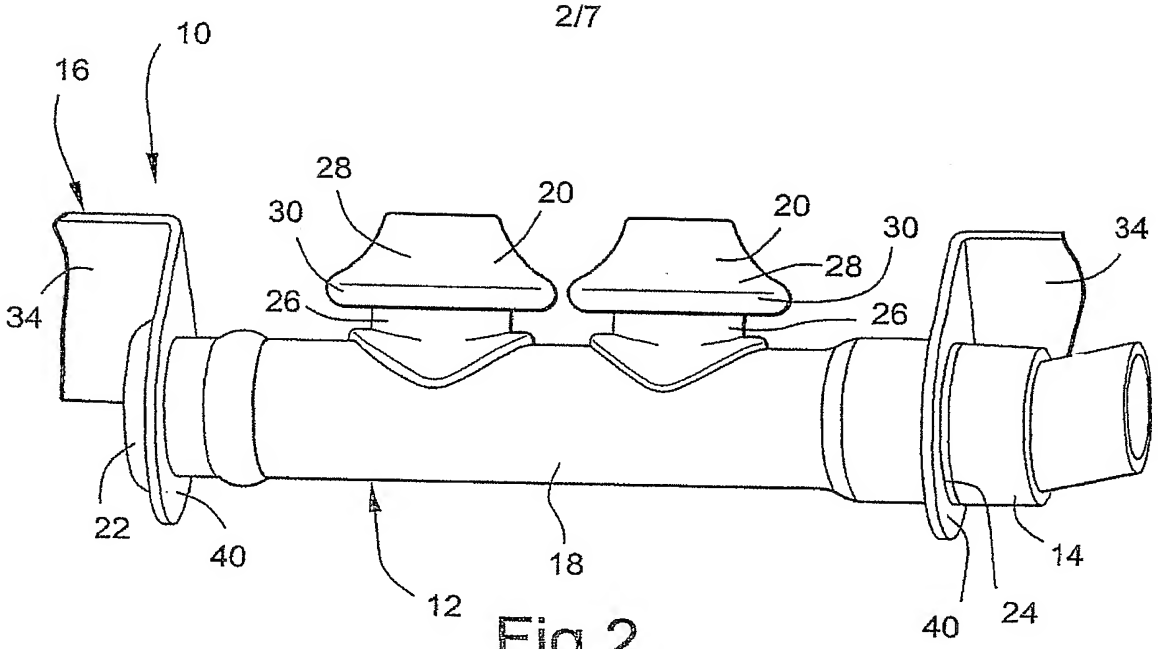
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Fig.2

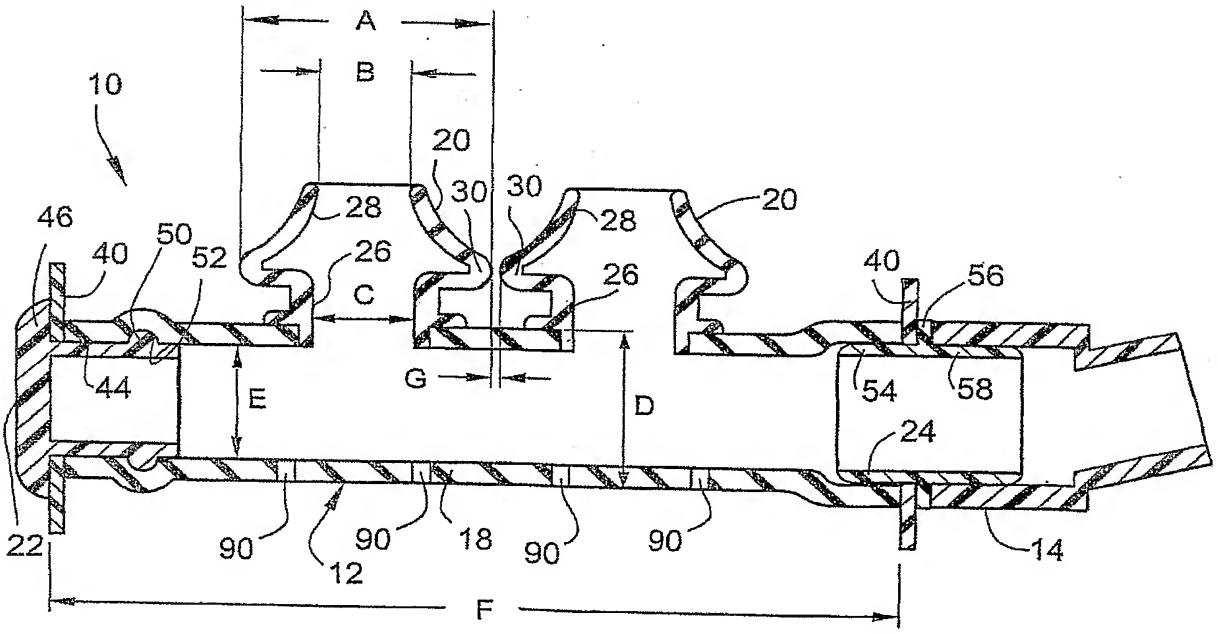
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Fig.3

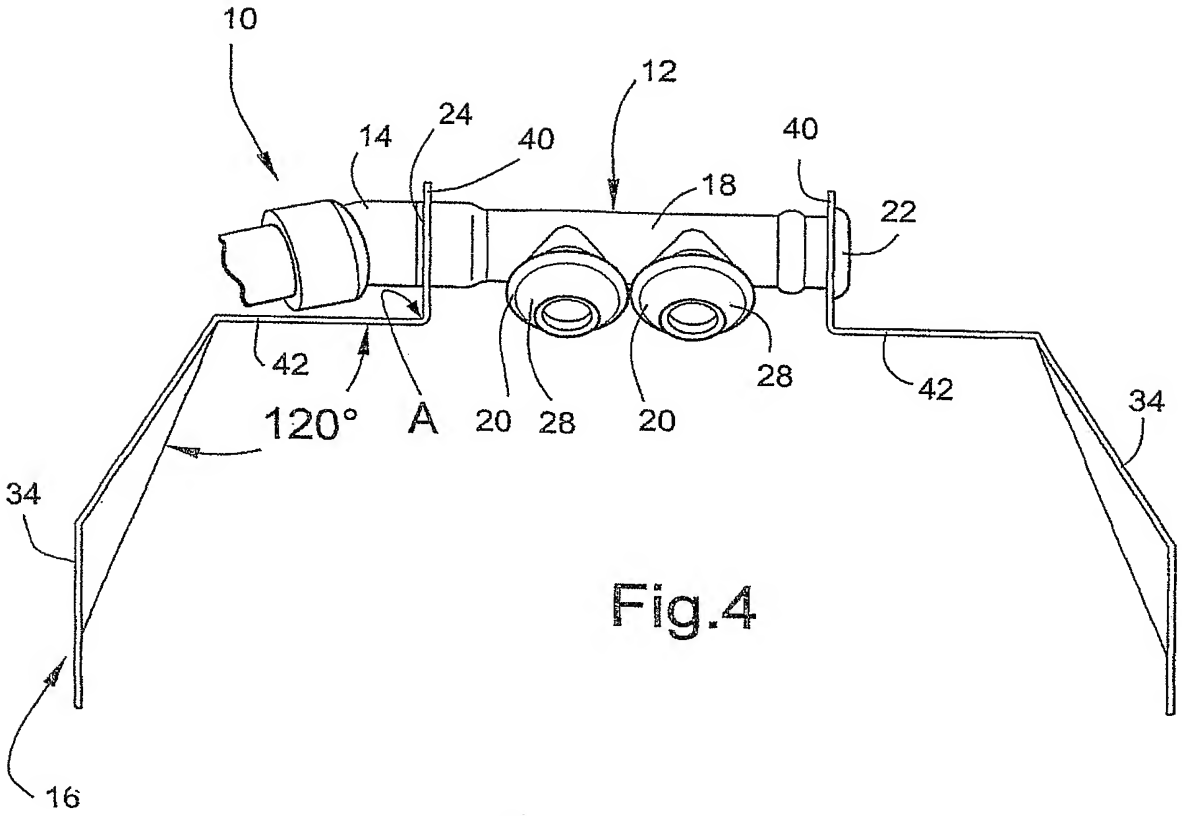
10
12
14
24
40
40
18
22
42
120°
A
20
28
20
28
42
34
34
16

Fig.4

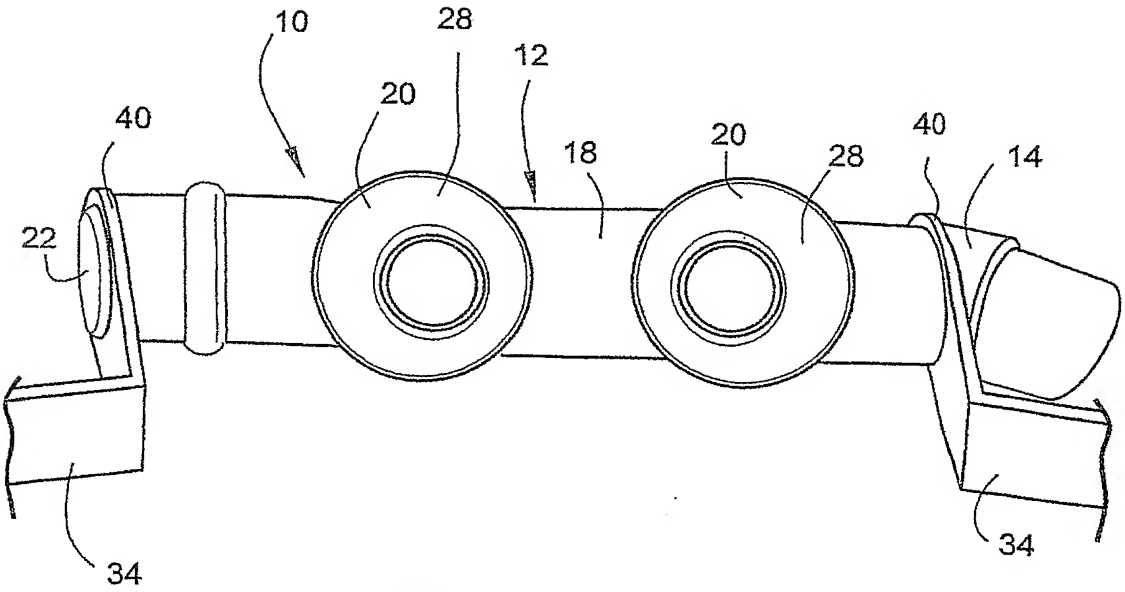
10
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Fig.5

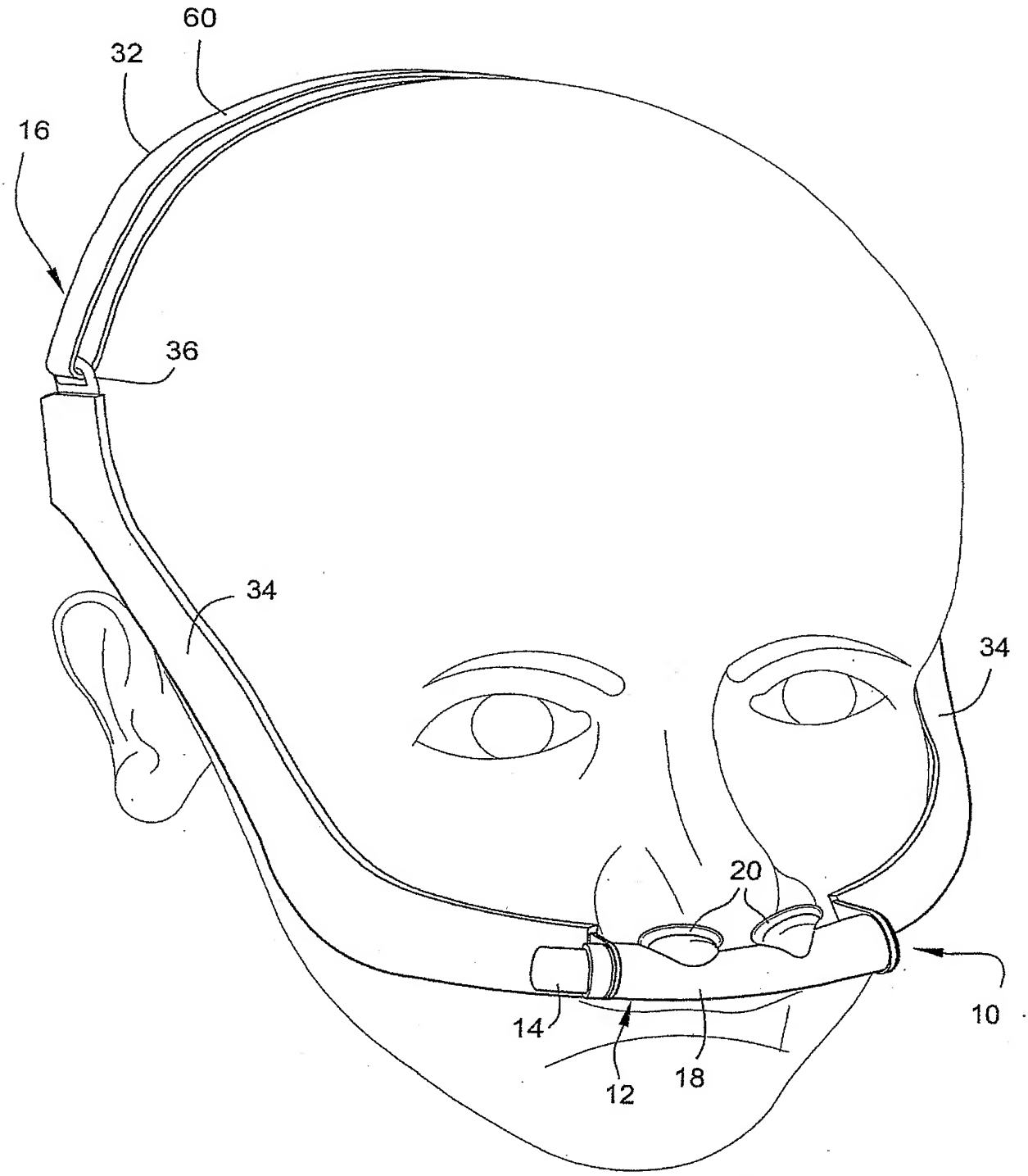

Fig.6

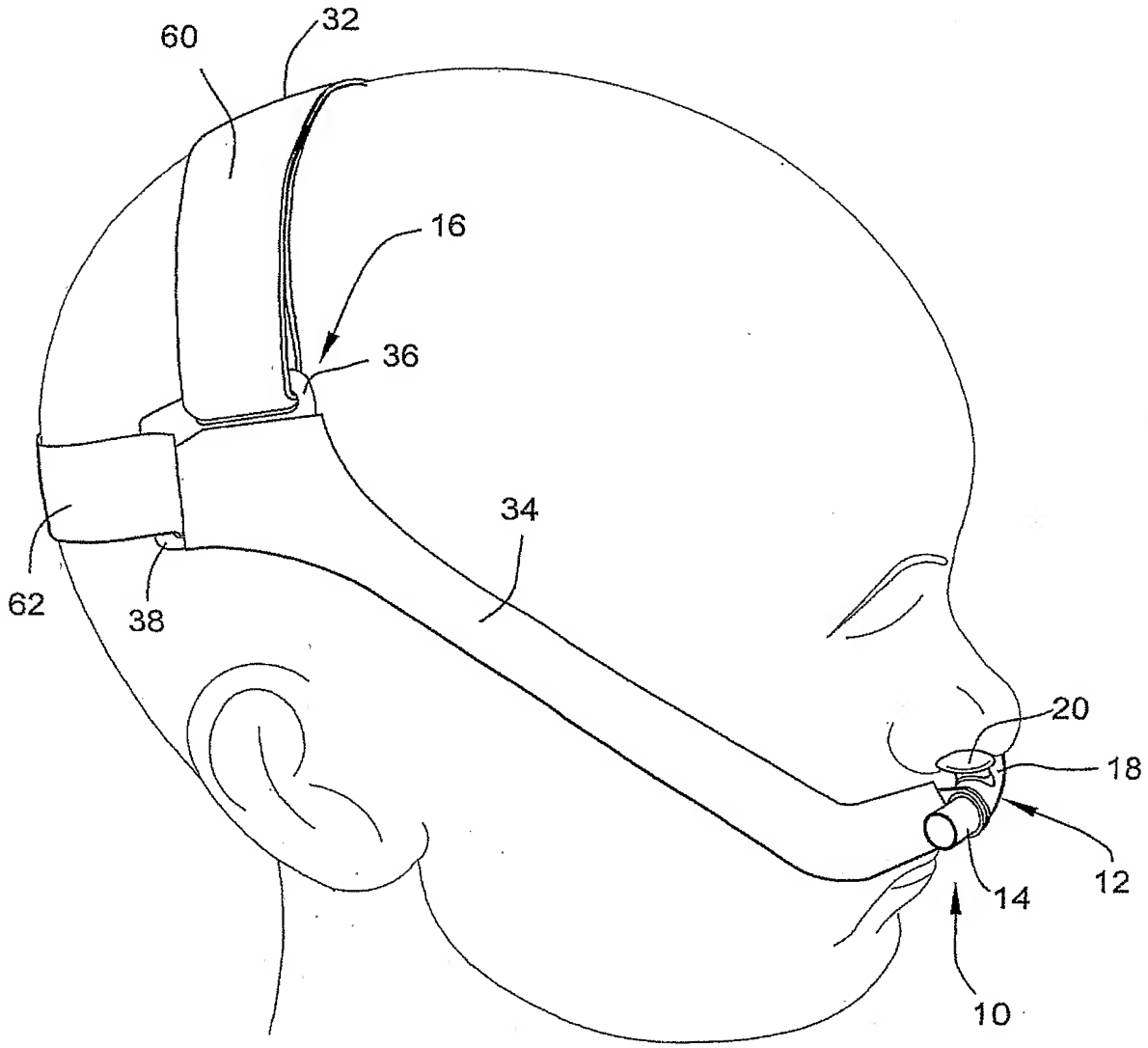

Fig.7

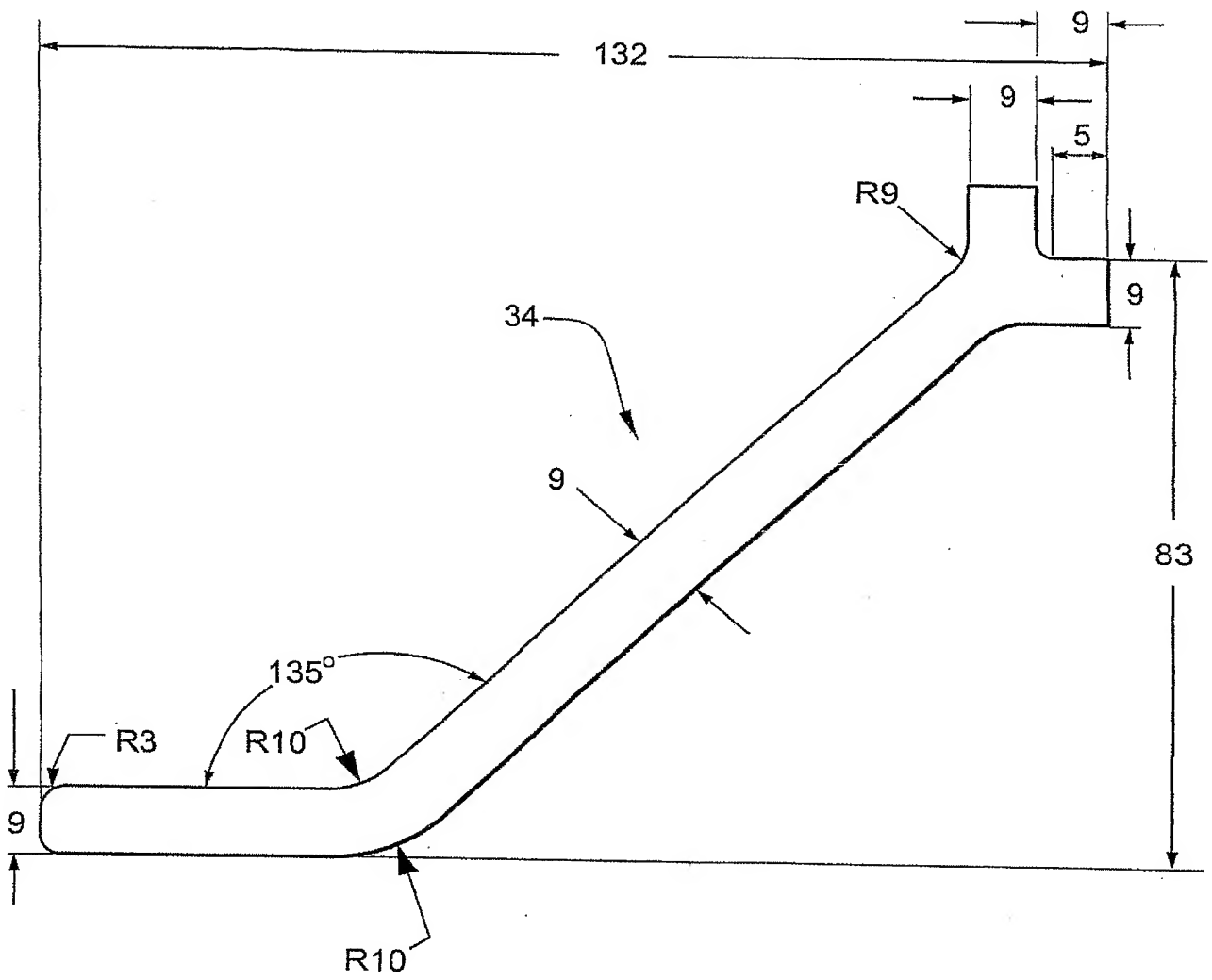

Fig.8

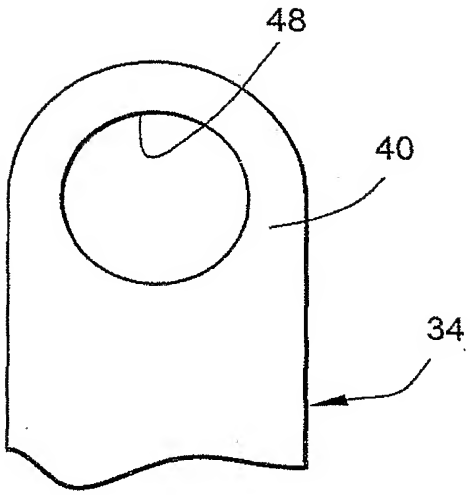

Fig.9

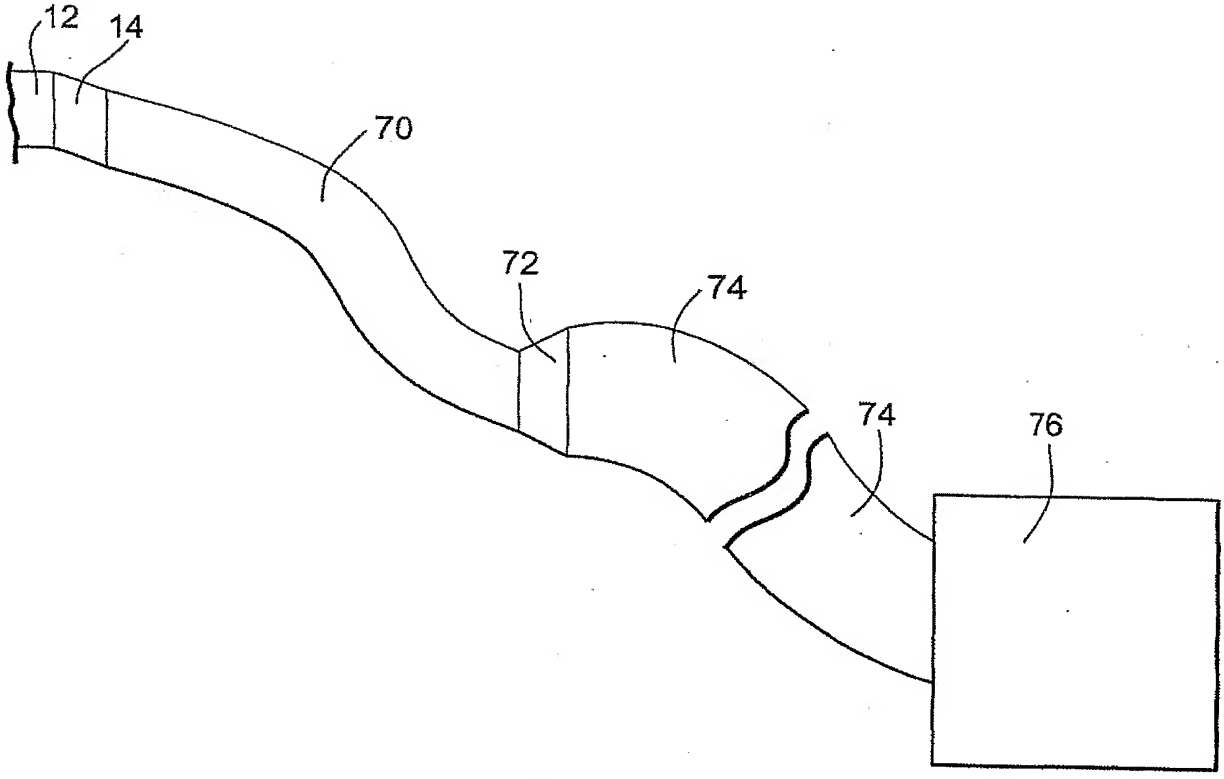

Fig.10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001494

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/06 (2006.01) ***A62B 9/00*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: IPC A61M 16/-; A62B 9/- & keywords: (nose, nares, nostril, mask, interface, nozzle, outlet, tube, duct, pipe, opening, passage, headgear, strap, band) and similar terms.
Espace: (nasal and assembly); (nasal and mask); and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0226566 A1 (GUNARATNAM ET AL) 18 November 2004 Whole document	1-33
X	US 2004/0020493 A1 (WOOD) 5 February 2004 Whole document	1-33
X	US 2005/0028823 A1 (WOOD) 10 February 2005 Whole document	1-33

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
06 November 2006	17 NOV 2006
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **KAREN VIOLANTE** Telephone No : (02) 6283 7933

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001494

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0028821 A1 (WOOD ET AL) 10 February 2005 Whole document	1-33
X	WO 2004/073778 A1 (RESMED LIMITED) 2 September 2004 Whole document	1-33
X	US 6478026 B1 (WOOD) 12 November 2002 Whole document	1-33
Y	US 2005/0061326 A1 (PAYNE, JR) 24 March 2005 Whole document	1-33
Y	WO 2005/016402 A2 (INNOMED TECHNOLOGIES) 24 February 2005 Whole document	1-33
X	WO 2005/063328 A1 (RESMED LTD) 14 July 2005 Whole document	1-26, 28-33
P,X	WO 2005/097247 A1 (RESMED LIMITED) 20 October 2005 Whole document	1-33

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001494

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-25 and 28-33 are directed to a nasal assembly and a breathing system. It is considered that the hollow body being bendable to adjust a position of the nozzles in use comprises a first distinguishing feature.
- Claims 26 and 28-33 are directed to a nasal assembly and a breathing system. It is considered that the outlet opening having a circular shape comprises a second distinguishing feature.
- Claims 27 and 28-33 are directed to a nasal assembly and a breathing system. It is considered that the patient interface only contacting the patient's face only at the nose and below the nose in use comprises a third distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is that each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. However this concept is not novel in the light of: US 2004/0226566 A1 (Gunaratnam et al).

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

The International Searching Authority believes that a search and examination for the second and third invention will not involve more than negligible additional search and examination effort over that for the first invention and so no additional search fees are required in order to search and examine those inventions.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2006/001494

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	2004226566	AU	2004212633	CN	1750854	EP	1603619
		US	2006137690	WO	2004/073778		
US	2004020493	AU	13555/02	CA	2364183	CA	2368825
		CA	2416410	EP	1317940	EP	1317941
		US	6478026	US	6595215	US	6776162
		US	6807967	US	6863069	US	6994089
		US	6997177	US	7059328	US	2002059935
		US	2002092527	US	2003116163	US	2005028823
		US	2005034730	US	2005039757	US	2005126574
		US	2005133039	US	2005235999	US	2005236000
		US	2006150982	WO	2005/016402	WO	2005/016407
US	2005028821	AU	2003258103	US	6997187	US	7000613
		US	2005045182	US	2005051177	US	2005133040
		WO	2005/016425	WO	200/5025354	WO	2005/025657
WO	2004/073778	AU	2004212633	CN	1750854	EP	1603619
		US	2004226566	US	2006137690		
US	6478026	AU	13555/02	CA	2364183	CA	2368825
		CA	2416410	EP	1317940	EP	1317941
		US	6595215	US	6776162	US	6807967
		US	6863069	US	6994089	US	6997177
		US	7059328	US	2002059935	US	2002092527
		US	2003116163	US	2004020493	US	2005028823
		US	2005034730	US	2005039757	US	2005126574
		US	2005133039	US	2005235999	US	2005236000
		US	2006150982	WO	2005/016402	WO	2005/016407
US	2005061326	US	6938620	US	2004025885	AU	13555/02
		CA	2364183	CA	2368825	CA	2416410
		EP	1317940	EP	1317941	US	6478026
		US	6595215	US	6776162	US	6807967
		US	6863069	US	6994089	US	6997177
		US	7059328	US	2002059935	US	2002092527
		US	2003116163	US	2004020493	US	2005028823

		US	2005034730	US	2005039757	US	2005126574
		US	2005133039	US	2005235999	US	2005236000
		US	2006150982	WO	2005/016402	WO	2005/016407
WO	2005063328	AU	2004308536	EP	1701759		
WO	2005097247	US	2005241644				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX